New Policies, Processes, and Regulations in the DUHS IRB

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Presentation Outline

- New and Revised IRB Policies/Processes
  - Appropriate personnel to consent subjects
  - Adding volunteers to the study team
  - Use of Duke data by former Duke employees/students
- eIRB Revisions Recent and Future
  - Closing an exempt study
  - Pathway for emergency use of test article
- New Federal Regulations/Guidance Affecting Research
  - In vitro assays as IDEs
  - Component analysis

Appropriate Study Personnel to Conduct the Consent Process

This policy clarifies that appropriately trained and qualified personnel to conduct the consent process have:
- completed CITI modules and are listed on Key Personnel
- possess sufficient knowledge of the study
- completed all relevant DOCR training

This policy clarifies that the following are inappropriate personnel to conduct the consent process:
- volunteers
- undergraduates
- minors
- administrative support personnel
- team members with COI
Addition of a Volunteer to a Study Team

1. All unpaid interns and volunteers on research teams must be adults (18 yrs. or older).
2. All unpaid interns/volunteers must complete the CITI modules.
3. A clean criminal background check must be obtained on each unpaid intern/volunteer. Note that the background check is not required for Duke students.
4. The Volunteer Agreement letter must be completed by the study team and signed by the unpaid intern/volunteer.
5. An email must be sent to your CRU medical director containing the following:
   - Unpaid Intern/Volunteer Name
   - Pro# of study
   - PI
   - Specific description of the individual’s role on the study and expected time on study team
   - Please ask the CRU medical director (or designee) to respond with an approval/sit back email.

Addition of a Volunteer to a Study Team (cont’d)

A personnel amendment must be submitted in eIRB to add the unpaid intern/volunteer to external key personnel for each study on which he/she participated. The amendment must contain copies of:
   - Signed volunteer agreement letter
   - Approval (email) from CRU Medical Director
   - Statement that a clean criminal background check has been obtained

Once the IRB has approved the personnel amendment, the unpaid intern/volunteer may join the study team.

Things to Remember About Unpaid Interns and Volunteers

Unpaid interns/volunteers will not have access under any circumstances to a subject’s or patient’s medical record.

Unpaid interns/volunteers may be granted Duke email accounts and access to shared drives specified by the PI.

All work by the unpaid intern/volunteer must be conducted on-site under the supervision of the PI or other designated study team members.

All work by the unpaid intern/volunteer must be conducted on Duke computers and servers.

No remote access and no use of personal electronics for storage or manipulation of study data.
When an Investigator Leaves Duke and Wants to Take Materials

Basic Fact #1
Materials derived or created at Duke are owned by Duke not by the individual investigator. Materials include:
- data
- samples
- transgenic animals
- drugs or devices
- processes (eg, novel surgical procedures)
unless ownership has been otherwise defined in the legal agreement between Duke and the sponsor.

Any intended transfer of Materials to an external entity (other than a study sponsor) should involve consultation with OCRC regarding the need for a transfer agreement.

Basic Fact #2
Entities that are engaged in research with human subjects require IRB oversight. Institutions are considered ‘engaged in research’ when working with identifiable data or samples. Work with de-identified or anonymized data/samples does not require IRB oversight – only a declaration of exemption from further IRB review by the IRB.

It is simpler for all parties concerned if a departing investigator can work with de-identified or anonymized data/samples at his/her new institution. This will dramatically reduce the number of agreements (confidentiality, transfer, etc.) and IRB approvals needed.


When an Investigator Leaves Duke and Wants to Take Data (cont’d)

When identifiable data/samples are required by the departing investigator:

1. Check the consent form for permitted disclosure of identifiable data. (It most likely will not allow disclosure outside of DUHS.)

2. Direct identifiers can be disclosed outside of DUHS via 2 methods:
   - re-consent; or
   - waiver of consent/HIPAA granted by the IRB.
   Caution: Do not assume the IRB will grant the waiver. It’s very difficult to convince the IRB that data derived from a retrospective review requires direct identifiers.

3. Indirect identifiers can be disclosed outside of DUHS via creation of a Limited Data Set and execution of a Data Use Agreement.
When an Investigator Leaves Duke and Wants to Take Materials (cont'd)

Points to Remember when arranging for Materials to be transferred to a former Duke employee/student:

1. The Materials are the property of Duke (or another entity as defined in previous legal agreements).
2. Transfer of unlinked de-identified or anonymized Materials is encouraged.
3. Direct Identifiers ≠ Data Use Agreement
4. Direct Identifiers = IRB oversight/approval

Relevant Information about Waivers

The IRB can only grant of waiver of consent/HIPAA authorization if the following conditions are met:

- It is impracticable to re-consent the research subjects.
- The research cannot be conducted without the waiver, and the listed identifiers are required to conduct the research.
- The risks to subjects, including risks of inadvertent disclosure, are minimal.
- The waiver will not adversely affect the rights and welfare of the subject.

Relevant Information about Direct Identifiers

A Limited Data Set cannot contain direct identifiers. The following are considered direct identifiers:

- Name
- Address/phone/fax
- SSN
- MRN/Health Plan #s
- Full facial image
- Audio/video recordings
- URL/IP addresses
- Device IDs
- Serial numbers
- Cert/license #s
- Fingerprints

If a departing investigator requires any of the identifiers above, a Data Use Agreement cannot be used. IRB oversight is required.
Information about Indirect Identifiers

A Limited Data Set can contain indirect identifiers. The following can be considered indirect identifiers:

- City/State
- Zip Code (first three digits)
- Medical interventional dates
- Age in years (up to 90 and greater)
- Race
- Gender
- Date of birth or death

eIRB Programming Changes

Closing an Exempt Study

An exempt study can now be closed with the simple click of a button. A completed final progress report is no longer required.

Emergency Use Pathway

Emergency Use of a test article now has its own review pathway in eIRB. The reviewing IRB Chair will, upon review completion, issue a statement that the planned intervention is consistent with all regulations governing its use.

eIRB Programming Changes to Come

Changes to the eIRB roll out every quarter. Programming priorities are set at a weekly meeting involving members of the IRB office and DHTS.

Planned changes:
- Removal of ‘None’ from CRU choices
- Continued embedding of summary elements into submission form
- Exploration of electronic Consent platforms
A Few Important Points to Remember about Emergency Use of a Test Article

1. The PI can always act without IRB review when the patient is in an immediately life-threatening situation and inform the IRB after-the-fact. A consent form is required if feasible.

2. An emergency use can only occur one time. Repeated use requires a Treatment Use/Compassionate Use protocol approved by a convened IRB.

3. The IRB Chair reviewing an EU cannot issue approval; only the convened IRB can do that, and only before the event.

Consult the policy entitled “Emergency Use” on the IRB’s website for full details and requirements.


FDA is looking more closely at in vitro diagnostic devices. If a research study proposes determining the safety and efficacy of an investigational in vitro diagnostic device, the study team and IRB are required to evaluate the need for an IDE.

Please use the IDE checklist provided on the IRB’s website to determine if an IDE is needed.

Conditions prompting evaluation of the need for an IDE:
- invasive sampling; potential for harm
- device results could potentially drive treatment

Devices that might require an IDE: biomarker assay, genomic profiling model, software algorithm that determines treatment

Investigational Device Alternatives

IDE
- oversight by, and reporting to, FDA
- DTMI training

Abbreviated IDE
- oversight by IRB-of-Record
- Subject to FDA regulations; reports to IRB

Exemption from IDE requirements
New FDA Guidance/Draft Guidance: Component Benefit Analysis

FDA has issued draft guidance concerning the need for separate benefit analysis for each of the components of a research study when randomization occurs. This currently affects only studies involving children.

Example: Subject is randomized to either standard care or investigational drug. The consent form must describe the risks/benefits of both investigational drug and standard care.

Example: Subject is randomized to either investigational drug or placebo. The consent form must describe the risks/benefits of both the investigational drug and the placebo.

NOTE: “lack of exposure to risks of investigational drug” is not an acceptable benefit of the placebo arm.

Top Five Issues Most Likely to Cause You and the IRB Trouble

1. Inappropriate disclosure of PHI outside of Duke
2. Lack of appropriate IND/IDE documentation
3. Inappropriate recruiting strategies
4. Incarceration of an enrolled subject without approval for inclusion of prisoners.
5. Lack of accuracy in describing risk/benefit in consent form

For Help, Contact……

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